Optimising team functioning, preventing relapse and enhancing recovery in crisis resolution teams: the CORE programme (CRT Optimisation and Relapse prevention)

CORE Phase 4: Evaluation of implementation of a CRT Resource Kit

Protocol Version 1.2, 11/03/14

Background

Crisis Resolution Teams (CRTs) – sometimes called home treatment or crisis assessment teams - provide rapid assessment in mental health crises and offer intensive home treatment as an alternative to acute admission if feasible[1]. The introduction of CRTs, mandated by the NHS Plan in 2000[2], has been an extensive change in the UK national community mental health care system. In 2000, few areas had such teams. Now they are available in every Trust in the country and several thousand mental health professionals have migrated into them[3]. When CRTs first became national policy, their evidence base was criticised as scanty[4,5]. However, some positive findings have now been reported, suggesting CRTs reduce inpatient admissions[6-10] and healthcare costs[11,12] and increase service user satisfaction with acute care[6,9].

Despite these indications of CRTs' potential effectiveness, considerable reservations have emerged about the model's delivery in routine settings, especially in two recent reports by the National Audit Office and Healthcare Commission[13,14]. Both ward managers and CRT leaders still view a significant minority of hospital admissions as unnecessary[15]. Impact on bed use appears to vary considerably between areas[10,13] and reductions in bed days tend to be less marked than those in admissions[8,10]. Service users and carers, whilst in the main positive about being able to receiving care in their own homes, report important areas of dissatisfaction with CRTs[13,16], especially regarding continuity of care, the quality relationships with staff and a narrow range of support on offer focusing too exclusively on medication and short term symptom control. The CRT model is currently loosely specified, with only limited evidence available regarding critical ingredients and specific interventions associated with good outcomes[17]. A survey of CRTs in 2005/6[18] reported considerable variation in CRTs resources, organisation and service delivery. This was confirmed by a

recently completed service evaluation of all CRTs in England conducted in 2012 for an earlier phase of the CORE study.

The US National Evidence Based Practice Project[19] offers a model for evaluating complex service-level interventions and promoting quality improvement in mental health settings. Two key elements of the EBP approach are: service reviews using a fidelity measure which assesses how far services are achieving a model of good practice; and utilisation of an implementation resource kit consisting of guidance, training materials and coaching and support for service managers and staff, designed to help services address areas where high model fidelity has not been achieved. The EBP programme has successfully developed fidelity measures and implementation resources for a range of service-level interventions including Supported Employment, Assertive Community Treatment and Integrated Treatment for patients with dual diagnoses[20,21]. CRTs are comparable with models in the EBP project in that we have some evidence for their efficacy in the right conditions, but a CRT fidelity measure and implementation resources have not previously been developed.

An earlier part of the CORE Study, a research programme funded by the UK Department of Health through the National Institute for Health Research Programme Grants for Applied Research (RP-PG-0109-10078), involved developing a CRT fidelity measure. Development work, including a review of research evidence and government and expert guidelines, interviews with all key CRT stakeholder groups and a survey of CRTs in England regarding service organisation and delivery, was used to develop a 39-item CRT fidelity measure. This has been piloted and used to survey CRT model fidelity across CRT teams in England. It will also inform the development and evaluation of a CRT implementation resource kit designed to help CRT services achieve high model fidelity and quality improvement. We wish to test the utility of the CRT resource kit in helping CRTs achieve high model fidelity and improve outcomes in the next phase of the CORE study, CORE Phase 4.

Aims

CORE Phase 4 involves a pilot trial of implementation a CRT resource kit. 15 CRTs will be randomised to receive the resource kit over a one-year period; 10 control CRTs will not receive the resource kit. The study aims are:

- To evaluate the impact of implementing a CRT resource kit on service users' experience of CRT care and acute service use
- To investigate whether CRT fidelity scores rise following resource kit implementation
- To investigate associations between CRT fidelity score and CRT service outcomes

- To investigate the impact of implementing a CRT resource kit on CRT staff morale and job satisfaction

The primary study outcome is service user satisfaction with CRT care, measured using the Client Satisfaction Questionnaire[23].

We hypothesise that:

- CRT service users' satisfaction with CRT care will be greater in CRTs receiving the resource kit, compared to control CRTs
- CRT fidelity score will rise in CRTs following resource kit implementation
- CRT service users' perceived continuity of care will be greater in CRTs receiving the resource kit, compared to control CRTs
- Hospital admissions, compulsory admissions and inpatient bed days (all adjusted for population size and for baseline scores on these measures) will be fewer in CRTs receiving the resource kit, compared to control CRTs;
- Readmissions to acute care and compulsory admissions over 6 months follow up will be fewer for service users admitted to CRTs receiving the resource kit, compared to control CRTs
- CRT staff job satisfaction, morale and psychological flexibility will be greater in CRTs receiving the resource kit, compared to control CRTs
- CRT fidelity score will be associated with better outcomes on measures of service user satisfaction and inpatient service use

Methods

i) The intervention

The CORE CRT resource kit will follow the model developed by the US Evidence Based Practice Program[19] for achieving high-fidelity implementation of a complex intervention or service model, leading to service improvement and better service outcomes. The resource kit will include written resources and guidance and ongoing coaching, mentoring and support from local facilitators and the study team, applied as appropriate to meet target areas for fidelity improvement in each individual service over a 1 year study intervention period. Following current guidance from the US EBP model[22], the CORE CRT resource kit will include the following:

- A written/electronic resource kit manual, including: a clinicians' manual, with practical resources and help to implement interventions in the CRT fidelity scale; and a managers' manual with guidance about implementation strategies to promote good model fidelity within the team.

- Fidelity reviews at baseline, six months, and at the end of the 12 month study period, with feedback from the external reviewers on the resulting fidelity report to the CRT manager and team. Fidelity reviews involve a one-day review by three external reviewers, following procedures previously submitted to Camden and Islington LREC and approved as audit. The reviewers produce a fidelity report, scoring the CRT on 39 items relating to CRT best practice and summarising service strengths and target areas for service development. This will be used as a means to focus attention on targets for service improvement and planning for how to achieve them.
- A local facilitator: Participating NHS Trusts will fund a local facilitator with dedicated time (0.1 full time equivalent per CRT implementing the resource kit) to promote CRT model fidelity through discussion and coaching of the CRT manager, mentoring, supervision and training of CRT staff and liaison with senior Trust management regarding resources or organisational support required to achieve model fidelity. The local facilitator may either be an employee of the participating Trust or an external consultant identified by the study team, depending on local resources and preferences. They might typically be a manager or senior clinician with experience of working in or with CRTs. Facilitators will be provided with training and coaching by appropriately experienced members of the research study team.
- A local implementation committee: a working group will be established in each CRT in the trial intervention arm to plan and support resource kit implementation. This group will include the CRT manager, local facilitator and other key CRT stakeholders as available, e.g. the consultant psychiatrist and other senior CRT staff, senior Trust managers, a representative of the local service user group. The working group will develop and review a local implementation plan in bi-monthly meetings.
- A Learning Collaborative: We will seek to engage senior managers from all participating Trusts in supporting resource kit implementation through an online forum, regular bulletins from the study team about implementation progress at study sites, and at least two Learning Collaborative meetings during the study period Through these structures, fidelity gains and locally-audited outcome successes and improvements will be reported. They will provide a forum for information sharing, problem-solving and networking at a senior level to promote organisational support for achieving high model fidelity in participating services. Learning and sharing of implementation strategies will be supported online through the study website.

Services in the control group will receive a fidelity review and written report at baseline and at the end of the study period, but no other implementation support.

ii) Setting

Twenty five CRTs will be recruited for the trial. CRTs will be selected from NHS Trusts within four Mental Health Research Network Hubs (North London, South London and the South East, West of England and Heart of England) to reflect a range of Trusts and areas, including urban and more rural services.

iii) Sample

Sample size: A sample size calculation for the primary outcome measure (service user satisfaction measured using the Client satisfaction Questionnaire[23]) determined the size of the service user sample. A sample of 375 participants (225 from 15 CRTs which have implemented the resource kit; 150 10 CRTs which have not) will give 97% power to detect a half a standard deviation difference in mean satisfaction (3.5 points assuming a typical S.D. of 7.0), and 80% power to detect a small difference of just over a third of a standard deviation, allowing for a moderately large within-team correlation of 0.05. Cohorts of patients equal in size to these will also be interviewed before the introduction of the resource kit, allowing assessment of whether there are baseline differences between the two groups of teams for which adjustments should be made.

A) Service user interviews

At each CRT, 15 service user participants will be recruited at baseline and outcome time points (different sets of CRT service users at each time point) providing a total sample N=375 at each time point. At each service, we will screen and recruit consecutively admitted, eligible, consenting service users until we reach our target of 15. Eligibility criteria for participants are:

- Have used the CRT for at least 7 days
- Can read and understand English
- Have capacity to provide informed consent
- Do not pose too high a risk to others to participate (including being interviewed on NHS premises or participating by phone, email or online survey)

B) Patient Records data

At all CRTs, anonymised service use data will be collected from NHS Trust patient record systems regarding all acute hospital admissions for the geographical sector and bed use over a six month period at baseline and outcome time points. Anonymised data regarding readmissions to acute care (i.e. readmissions to acute impatient mental health wards, Crisis Resolution Teams or other NHS acute mental health services such as crisis houses or acute

day hospitals) over a 6-month period will be collected at baseline and outcome time points from patient record systems for all service users admitted to the CRT over a one-month period.

C) Staff questionnaires

At each CRT, all clinical CRT staff will be invited to complete a set of questionnaires at baseline and outcome time points measuring: staff morale, job satisfaction, general psychological health and psychological flexibility. An estimate of about 20 clinical staff per CRT would provide an overall sample of N = 500.

D) Staff interviews and focus groups

Following implementation of the resource kit, we will invite the local facilitator for each CRT receiving the resource kit to participate in an individual interview, exploring their experience of using the resource kit and their key role in trying to facilitate organisational change. Following these interviews and the study follow-up fidelity reviews, we will identify four CRTs as "case study" services: these will include services where fidelity scores and the local faciliator's feedback suggest that resource kit implementation was successful, and CRTs where this was not the case. We will then convene one focus group in each of these four CRTs. This will include where possible: the CRT manager, the CRT consultant psychiatrist and 6-8 staff from a range of professional groups and grades, to explore the CRT team's experience of the CRT resource kit implementation. If key informants (e.g. the CRT manager or Consultant Psychiatrist) are unable to attend a focus group, we will also seek to conduct individual interviews with them.

iv) Measures

A) Service user interviews:

Study researchers will use an interview schedule to complete a structured interview with study participants. This will include information about service users' characteristics and service use (such as age, gender, ethnicity, previous use of the CRT and inpatient admissions). It will also include two structured measures:

The Client Satisfaction Questionnaire (CSQ-8)[23]: This is an eight item questionnaire about the participant's satisfaction with the CRT service, with four possible answers given which participants have to circle one of them. Each question is scored from 1 to 4, with 1 indicating least satisfied and 4 indicating most satisfied. Individual item scores are summed to give an overall score between 8 and 32, with higher scores indicating greater satisfaction.

Continu-um[24]: This measure consists of 16 topics relating to perceived continuity of care, with responses given as five point Likert scales, scored 1 to 5, giving a possible range of 16 to 80, with higher scores indicating greater continuity of care.

B) Patient records data:

Study researchers will use a proforma to seek information from participating NHS Trusts' patient records systems at baseline and the end of the study. This will detail the information required, which will cover: number of hospital admissions and inpatient bed-use, and available summary demographic data for all patients within the CRT's catchment area during a six month period; and, for all patients admitted to the CRT during a one-month data collection period, readmissions to acute care, including compulsory and voluntary hospital admissions during a 6 month follow-up period, and length of stay with the CRT and in acute care.

C) Staff questionnaires

CRT staff will be given a structured questionnaire to complete and return to study researchers. This will include information about the participant's characteristics (age, gender, ethnicity, professional group and grade, experience in the NHS, in CRTs and in the current CRT team). It will also include the following measures:

The Work-Related Acceptance and Action Questionnaire[25]. This is a 7-item scale of work-related psychological flexibility.

The Work Engagement Scale[26]. This is a 9-item measure of positive work engagement.

The General Health Questionnaire[27]. This is a 12-item measure of general psychological health.

The Maslach Burnout Inventory[28]. This is a 22-item measure of staff morale, providing information about emotional exhaustion, cynicism, and perceived personal accomplishment.

D) Staff interviews and focus groups:

Topic guides will be developed for local facilitator interviews and CRT staff focus groups. These will explore participants' experience of the CRT resource kit, most and least helpful parts of the resource kit, barriers and facilitators to its implementation, and perceived impact of the resource kit implementation on CRT service delivery and outcomes.

v) Procedures

At each service, baseline data from Trust patient records will be collected for a six month period prior to study randomisation. The baseline CRT fidelity review and interviews with service users will be conducted within this 6 month period. Participating CRTs will then

randomised to the experimental or control arms of the study. Outcomes data from Trust patient records will be collected for a sixth month period 6-12 months following randomisation. Outcome interviews with service users and staff, and the end-of-study CRT fidelity review, will also be conducted between months 9-12.

CRT randomisation

The 25 teams will be randomised to either receive resource kit implementation (n = 15) or control (n = 10). Randomisation of CRTs will be stratified by NHS Trust. Randomisation will be conducted by statisticians from Priment, the UCL Clinical Trials Unit, who are not directly involved with the study.

Recruitment, consent and data collection

A) Service user interviews:

Identification of participants: Researchers will seek help from clinical staff in participating CRTs to screen and identify potential service user participants who meet the study's inclusion criteria. Consecutively admitted patients will be approached close to the point of discharge until a cohort of 15 has been obtained. The same process will be used for collecting baseline and outcomes data from different sets of service users. Clinical staff from the CRT or other community mental health services who are known to the patient will contact patients initially to explain briefly about the study and ask if the patient is willing to be contacted by a study researcher to discuss participation further. At this stage, clinicians will screen out service users who are unwilling participate in the study or who lack capacity to provide consent. For those patients who express willingness to be contacted by a researcher, clinical staff will pass on their name and contact details to a study researcher. The researcher will double check with the clinician at this point whether there are any limitations due to known risks on where meetings with the potential participant could take place. The researchers will keep a record of potential participants to be contacted and the date and the name of the clinician with whom this was agreed. Researchers will ask the clinician who spoke to each patient to note the patient's agreement to be contacted by a researcher in their patient records.

Recruitment and consent: A study researcher will then contact potential participants to explain what the study involves and answer any questions. For those still willing to participate, the researcher will send a written information sheet about the study, then contact potential participants again to seek consent to participate. At this point, the researcher will check the participant has understood the information sheet and continued capacity to consent.

Potential participants will be offered the choice of completing the study questionnaire in person with a researcher, by email or as an online survey (using UCL's secure "Opinio" system, or as a telephone interview. Consent to participate will accordingly be obtained in one of three ways:

i. A researcher will obtain the participant's signed, written consent at a face-to-face meeting.
ii. The participant completes a study consent form (potentially without a hand-written signature) and returns it to the study researcher by email. In this circumstance, the returned consent form and accompanying email would be kept and stored by the study researchers.
iii. The participant may provide verbal consent by telephone. In this circumstance, the study researcher would audio-record the process of obtaining verbal consent, which will involve seeking confirmation that the participant has received a copy of the study information sheet, and confirmation of agreement to each item on the study consent form. In this circumstance, the researcher would store the audio-file securely online on a secure University network, identified by the participants study ID. A written record of the participant's verbal consent and stored audio-file would also be made and stored.

Payment: Participating service users will be offered a gift of £10 in acknowledgement of their time and help with the study. The method of delivering this payment will be agreed with the service user in advance, when consent is taken. Options include a) providing £10 in cash at the completion of a face-to-face interview; b) delivery of an Amazon e-voucher by email or post; c) delivery in person of £10 in cash by a study researcher at a time to be arranged between the researcher and the participant following participation by phone or email.

Once consent to participate in the study has been obtained, a study researcher will complete the study measures with all participants as a structured interview or self-completion questionnaire. The interview will take about 15 minutes to complete.

In order to maximise response rates and the representativeness of our service user samples, we have sought permission for service users to participate by phone, email, online survey or meeting a researcher in person, having given verbal or written consent. Seeking verbal consent to participate in research as a means to enhance response rates has precedent in nationally-funded health services research studies with participants with mental health problems, such as the Cadet Study[29]. It is consistent with National Research Ethics Service guidance[30] (NRES 2011 s.11.2.4) that consent may be "written, oral or non-verbal" and that a written signature is not necessarily required. The information collected from service users

in this interview is brief and concerned with participants' views about CRT services, rather than more personal information about their own health or circumstances (apart from very brief demographic information about age, gender and ethnicity). It is similar in nature to information collected from service users without written consent by NHS clinical services as part of routine service evaluation, for instance in the NHS Friends and Family Test[31]. We therefore consider that, given ethical approval, it is proportionate to collect this data with verbal or written consent from participants (following initial screening and information from clinical staff), by phone or email rather than in person if the participant prefers.

B) Data from Trust patient records systems

When CRTs are identified to participate in the study, the research team will confirm approval from participating Trusts and the availability of required data from Trust information systems. For baseline and study outcomes data from patient records, a study researcher will contact the appropriate administrators or informatics team within each Trust. The study researchers will provide a pro forma which specifies clearly the nature of information and time periods for which data are required. Administrators will then be asked to provide the data to the research team in anonymised form, so researchers are never aware of the names of individual patients to whom the data refers.

C) Staff questionnaires

A study researcher will visit the CRT team in advance to publicise the study and answer any questions the staff team have about their involvement. At each participating CRT, a study researcher will seek a list of all CRT clinical staff from the CRT manager at baseline and outcome time points. The study researcher will then assign a study identification number to each staff member. A master document linking CRT staff names to ID numbers will be stored securely at the research study office. An envelope will then be sent to all CRT staff containing:

a) a letter inviting them to participate in the study by completing the questionnaire

b) an information sheet about the study

c) A copy of the structured questionnaire, with the staff member's ID number already recorded. (This questionnaire will not ask staff to record their name anywhere.)

d) An envelope addressed to the study researcher for the staff member to leave their completed questionnaire at a pre-arranged place in the CRT or directly to the study researchers.

By these means, no collected data will be individually identifiable at any stage. Staff will give their consent to participate in the study by completing the questionnaire. Study researchers will track which staff have completed questionnaires at each service and prompt non-responders verbally or via email. If a staff member says they do not wish to complete the questionnaire, no further prompts will be made.

D) Staff interviews and focus groups

A study researcher will contact local facilitators directly to invite them to participate in an individual interview. Staff focus group participants will be identified initially through liaison with managers of participating CRTs. A study researcher will provide potential participants with written information about the study and the opportunity to contact the researchers with any questions about participating in the focus group. Staff will be informed that participation is entirely voluntary. Focus groups may take place in the CRT team or other convenient NHS premises. Written consent will be taken from focus group participants before the focus group begins. Focus groups will be facilitated by two researchers from the study team. Focus groups and individual interviews will be audio-recorded.

Data storage

All data recorded on paper forms will be stored securely at University College London or the University of Bristol(for data collected by study researchers based there) in accordance with university data protection procedures. Data collection forms will identify participants only by their study ID. Participant consent forms, contact details and a single master copy linking participants' names and IDs will be held separately from other data. All data will be held in locked filing cabinets in locked offices within university buildings.

Audio-recordings of staff interviews focus groups will be downloaded directly by the study researchers from the audio-recorder onto a folder only accessible to the research team on a secure network at University College London. Recordings will then be deleted immediately from the audio-recorder. Audio-recordings will be sent for transcription by a professional transcription company (as explained in the participant information sheet and consent forms).

Study researchers will develop and manage a secure database for all quantitative study data and store electronic copies of focus group transcripts on the secure IT network at University College London. Participants will be identified only by a study identification number in the database. Data will be entered by study researchers using secure log-ins. The study team will follow advice from Priment, the UCL Clinical Trials Unit regarding development and maintenance of the study database.

Once data collection is complete, all paper forms will be transferred to University College London. Data will be held securely by the study team for one year after the end of the study, then archived securely in accordance with University College London data protection procedures.

vi) Analysis

Service satisfaction and perceived continuity of care:

We will test the hypothesis that global satisfaction, measured by the Client Satisfaction Questionnaire[23] is greater in the teams that have implemented the resource kit than in those that have not. Experienced continuity of care, measured using Continu-um[24], will also be compared between those receiving and those not receiving the intervention.

Two main analyses will be carried out. First, we will test the hypothesis that mean total satisfaction with CRT care will be greater in teams that have introduced the CRT resource kit. Secondary outcomes for resource kit and control teams will be similarly compared. Second, we will explore, using a multilevel modelling approach, the extent to which team fidelity score can explain variations in individual satisfaction with care.

Service use:

We will use routine data from local electronic systems to compare change in service use patterns in each catchment area between the period before resource kit implementation and the period afterwards. The extent of this change will be compared between areas that have implemented the resource kit and the control areas that have not. Admission rate and bed use, adjusted for population size, will be measured over a 6 month period both before and after resource kit introduction in the experimental areas. We will also explore whether there is any evidence of differences between experimental and control areas in extent of change in rates of compulsory detention under the Mental Health Act and of readmissions within 6 months of an initial admission to acute care. Other routinely collected indicators of CRT functioning, such as referral sources and caseload composition will also be examined as part of an exploration of the impact of the resource kit on service use.

Staff questionnaires:

We will test the hypotheses that: a) mean staff psychological wellbeing, measured by the General Health Questionnaire; b) mean staff burnout, measured by the Maslach Burnout Inventory; and c) mean staff job involvement, measured by the Work Engagement Scale; are greater in CRTs receiving the resource kit than in control CRTs. We will use data collected

from CRT staff at study baseline, before the introduction of the resource kit, to assess whether there are baseline differences between the two groups of teams for which adjustments should be made.

In secondary analyses, we will explore whether staff psychological flexibility at baseline, measured using the Work-Related Acceptance and Action Questionnaire, predicts staff morale and job satisfaction following resource kit implementation, and whether psychological flexibility changes following resource kit implementation in CRTs receiving the resource kit, compared to controls. These secondary analyses, as well as forming part of the main study results, will be used as part of a PhD thesis by one of the research assistants working on the study, supervised by the study Chief investigator and Programme Manager.

Staff focus groups:

Qualitative data from interviews with local facilitators and focus groups with CRT staff from CRTs implementing the resource kit will be analysed using thematic analysis[32] aided by qualitative analysis software (Nvivo9). Thematic analysis will allow exploration of themes relating directly to our research questions and arising more inductively from the data. Analyses will be conducted collaboratively by a group of researchers within the team, to enhance the validity of the analysis.

Research Governance and Oversight

Ethical approval for the study and approvals from R&D departments and participating services in involved NHS Trusts will be obtained before the study begins. In addition to this, the Clinical Trials Unit at University College London – Priment – will advise on the development of the protocol and operating procedures for the study, including randomisation, data management and analysis plans. Priment will remain involved and provide advice throughout the course of the study. The trial protocol will be registered in advance with ISRCTN. A study steering group independent of the study team will be established. It will, include experienced mental health service researchers, clinicians with experience of Crisis Resolution Teams, a statistician, a health economist, and service users and a carer representatives. The steering group will meet before the study begins and regularly once or twice a year, to oversee the conduct of the study and provide impartial advice to the Chief Investigator.

Dissemination

Findings from the study will be written up in a final report for the study Funders (the National Institute for Health Research) and in peer-reviewed journals. Camden and Islington

NHS Foundation Trust, which manages the CORE programme, will maintain access to the CRT fidelity scale and Resource Kit beyond the end of the study: both will be freely available for use by NHS services.

Timescale

The proposed timeline for CORE Phase 3, subject to any delays with approvals or recruitment, is as follows:

December 2013 – March 2014	Submission of application for ethical approval to the REC R&D approval from participating NHS Trusts Contact and confirmation of participation from CRTs within participating Trusts Advice and approval from the Clinical Trials Unit for study operating procedures, randomisation and data management arrangements
March – October 2014	Collection of baseline data from all participating CRTs • Service user interviews • Staff questionnaires • 6-months admissions data from patient records • Baseline fidelity review
March – October 2014	25 participating CRTs randomised: 15 in the treatment arm to implement the resource kit; 10 controls
March 2014 – October 2015	Study intervention period: 1 year resource kit implementation in 15 CRTs
March – October 2015	Collection of outcomes data from all participating CRTs • Service user interviews • Staff questionnaires • 6-months admissions data from patient records • Outcome fidelity review
April 2015 – November 2015	Staff interviews and focus groups from 15 CRTs receiving the resource kit
By March 2016	Data analysis complete CORE study end date: 31.03.16

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